K052622

DEC 9 2005

510(k) SUMMARY

510(k) Owner :	Mickey Albergo (Business Manager)
Contact person :	Rich Garrett (Product Engineer)
Business address:	MACAN Engineering and Manufacturing Co. 1564 N. Damen Ave. Chicago, Ill. 60622 1-(773)-772-2000
Device Classification Name :	Unit, Electrosurgical, and Accessories, Dental
Device Proprietary Trade Name :	MACAN model MC-4A Dental Electrosurgical Unit
Regulation :	872.4920
Product Code :	EKZ
Classification :	class II
Owner/Operator :	MACAN Engineering and Manufacturing Co.
Owner/Operator Number :	1418975

Device description : The MC-4A dental electrosurgical unit is an AC powered device consisting of a controlled power source and a set of cutting and coagulating electrodes. The device is intended to cut or remove soft tissue or to control bleeding during surgery in the oral cavity. An electrical current passes through the tip of the electrode into tissue and, depending upon the operating mode selected, either cuts through soft tissue or coagulates the tissue.

Predicate Substantially Equivalent Device Legally Marketed : MACAN Radio Surgery MC6A

Device Classification Name :	Unit, Electrosurgical, and Accessories, Dental
Regulation :	872.4920
Product Code :	EKZ
Classification :	class II
510(k) Number :	050735

SUMMARY TABLE OF COMPARISON

Indications for Use	SAME
Electrical Output	SAME RATINGS
Electrodes	SAME same manufacturer, same part numbers
Accessories	SAME same manufacturer, same part numbers
Control Functions	SAME

It is reasonable to conclude, on the basis of the Summary Table of Comparison, that the MACAN model MC-4A dental electrosurgical unit is substantially equivalent to the cited predicate device. Note : the issue of electrode and hand piece material bio-compatibility is addressed within the submission for the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Mr. Mickey Albergo
Manager
Macan Engineering Company
1564 North Damen Avenue
Chicago, Illinois 60622

Re: K052622
Trade/Device Name: MACAN Model MC-4A Dental Electrosurgery Unit
Regulation Number: 872.4920
Regulation Name: Dental Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: EKZ
Dated: September 20, 2005
Received: September 27, 2005

Dear Mr. Albergo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K052622

Device Name: MACAN model MC-4A dental electrosurgery unit

Indications For Use:

Soft tissue management within the oral cavity to address the indications for incision, excision and coagulation to induce hemostasis in intra-oral soft tissue.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division Sign-Off

K052622